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10/743,192

12/22/2003

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06/09/2006

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EXAMINER

THALER, MICHAEL H

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3731

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Application Number: 10/743,192
Filing Date: December 22, 2003
Appellant(s): BONUTTI, PETER M.

Dana A. Brussel
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 20, 2006 appealing from the Office action mailed July 15, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

3,417,745

SHELDON

12-1968

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-4 and 7 stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sheldon (3,417,745). Sheldon, in figure 4, discloses a shaft. The claimed shaft is the inflation channel which is used for inflation of bladder 57 or 57a which is rigidified (or reinforced) by being attached to the spinescope (which is rigid as indicated in col. 2, lines 39-40 and 60-63). It is unclear if the inflation channels which are used for inflation of bladders 57 and 57a are within the body of the spinescope (in a manner similar to that shown for channel 80 in figure 2) or along the side of the spinescope (in a manner similar to that shown for channel 56 in figure 3) since the inflation channels are not shown in figure 4. In any event, locating a channel within the body of the spinescope, as shown in figure 2, has the self-evident advantage of preventing the

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channel from being inadvertently compressed and blocked by the surrounding tissue. It would have been obvious to locate the inflation channels for bladders 57 and 57a within the body of the spinescope so that this embodiment (figure 4) too would have this advantage. In either configuration, the inflation channel is rigidified by being attached to the rigid spinescope.

Alternatively, the claimed shaft is considered to be the combination of the inflation channel and the spinescope, which together form a shaft.

Sheldon also discloses inflatable bladder 57 or 57a which has the shape of a wedge upon inflation (as seen in figure 4, noting that bladder 57 or 57a tapers in the proximal direction). Alternatively, it would have been obvious that the inflatable bladder 57 or 57a has the shape of a wedge since it tapers in the proximal direction. The inflatable member 57 or 57a is inherently capable of separating adjacent portions of bone tissue upon inflation since it provides a relatively large outward force when it inflates, and since only a relatively small force is required to separate adjacent portions of bone tissue. The inflatable member 57 or 57a provides a relatively large outward force when it inflates for the following reasons:

First, bladder 57 or 57a is made of Mylar (col. 8, line 55-58) which is very strong and does not stretch when inflated and

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is the same material used in appellant's invention (page 7, lines 11-14 of appellant's specification). A balloon material which does not stretch upon inflation can apply significantly more force to surrounding material than an elastic, stretchable balloon (such as a toy balloon for example). This is because a stretchable balloon, when inflated and when encountering surrounding material, can expand in the areas of least resistance and "balloon out" in areas where there is no surrounding material. Thus, part of the balloon force is diverted to the open areas adjacent to the surrounding material (where it "balloons out") and the balloon can apply relatively little force to the surrounding material. This is exemplified by a toy balloon which is squeezed by a hand and which deforms and expands in areas adjacent to but not inside of the hand. In sharp contrast, a balloon made of inelastic material such as Mylar, when inflated and when encountering surrounding material, cannot expand in the areas of least resistance. This is because a balloon made of inelastic material will expand to a predefined, fully expanded shape and cannot "balloon out" in areas where there is no surrounding material balloon. Thus, substantially all of the inflation force will be applied to the surrounding material.

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Second, bladder 57 or 57a is filled with liquid (the fluid in the phrase "fluid or gas" referred to in col. 8, line 68) which is substantially non-compressible.

Only a relatively small force is required to separate adjacent portions of bone tissue to create a working space for the following reasons:

First, the types of bone are not defined in the claims. Some bones are easily separated with little force. For example, when many people pull on a finger or thumb (with very little force) and release it they feel the finger bone slightly separate from the adjacent bone in the palm and impact each other when the finger is released. Note that the amount of separation or the amount of working space created is not claimed. Thus, bladder 57 or 57a of Sheldon, if placed between these bones in a hand and inflated, would inherently separate them.

Second, the conditions of the connective tissue surrounding the bones are not defined in the claims. For example, the adjacent bones of a patient with completely torn ligaments would be very easily separated with little or substantially no force since no connective tissue holds the bones together. Thus, bladder 57 or 57a of Sheldon, if placed between these bones and inflated, would inherently separate them.

As to claim 7, Sheldon discloses cannula 5.

(10) Response to Argument

The allegation that Sheldon fails to disclose a shaft with an open distal end is unfounded. Clearly, the inflation tube of Sheldon has an open distal end since it communicates with the bladder 57 or 57a to inflate it as indicated in col. 9, lines 5-7. Alternatively, the claimed shaft is considered to be the combination of parts 2 and 56, which together form a shaft. This shaft has an open distal end (at the open distal end of inflation tube 56).

The allegation that Sheldon fails to disclose a cannula having a passage that receives the shaft to deploy the bladder at a target site in tissue is unfounded. Sheldon clearly discloses a cannula (the needle 5) having a passage that receives the shaft (the spinescope 7) noting col. 3, lines 10-13 and figure 1. Further, even when the shaft and bladder are within the needle with the distal end of the shaft and the bladder at the distal end of the needle (in the manner similar to that shown in figure 1), the bladder is deployed "in tissue" as claimed since the entire assembly is within the body and is thus "in tissue". Further, the bladder is at a target site in tissue since the intended location within the distal end of the needle as described in col. 3, lines 10-13 is a target site. In

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any event, Sheldon, in col. 9, lines 59-70, indicates that the spinescope with a bladder is inserted into a smaller needle to enter the extra-dural space, indicating that the smaller needle has an open distal end to permit such entry. Further, contrary to appellant's remarks, Sheldon, in col. 3, lines 6-10 indicates that the tip 5b consists only of the bottom wall 5c and side walls 5d and has no closing wall above bottom wall 5c. Thus, the open distal end above the bottom wall 5c is inherently capable of enabling the passage of the shaft 7 therethrough, particularly when the halves 6 and 6a are spread apart as described in col. 3, lines 28-33.

(11) Related Proceeding(s) Appendix

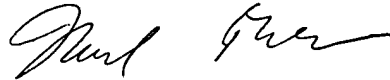
No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

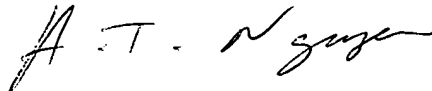
Respectfully submitted,

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